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TITLE: Caring Letters for Military Suicide Prevention: A Randomized Controlled Trial

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14. ABSTRACT The purpose of this multi-site study is to conduct a Department of Defense (DoD) Telemedicine and Advanced Technology Research Center (TATRC) funded randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among Service Members and Veterans. The "caring letters" concept was originally developed and evaluated by Jerome Motto and colleagues in the 1970's (1). In Motto's trial, civilian psychiatric inpatients were sent caring letters following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the Caring Letters group had a significantly lower suicide rate for the first two years of the trial. These "caring letters" are one of the only suicide prevention interventions to reduce suicide mortality in a randomized controlled trial. Despite the initial promising results of the original Caring Letters RCT, there have been no published replications of the intervention or tests of the intervention among military personnel or veterans. This study will fill an important gap in the evidence base for the Caring Letter intervention and is timely given the steady increase of military suicide in recent years.					
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## **Introduction:**

The purpose of this multi-site study is to conduct a randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among Service Members and Veterans. The “caring letters” concept was originally developed and evaluated by Jerome Motto and colleagues in the 1970’s (1). In Motto’s trial, civilian psychiatric inpatients were sent caring letters following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the Caring Letters group had a significantly lower suicide rate for the first two years of the trial. These “caring letters” are one of the only suicide prevention interventions to reduce suicide mortality in a randomized controlled trial (2). Despite the initial promising results of the original Caring Letters RCT, there have been no published replications of the original intervention or tests of the intervention among military personnel or veterans. This study will fill an important gap in the evidence base for the Caring Letter intervention and is timely given the steady increase of military suicide in recent years (3).

## **Body:**

All 6 sites have completed recruitment and enrollment of participants. A total of 1,319 participants are enrolled in the study. All participants have entered the follow up phase. A total of 431 follow up visits have been conducted with all measures completed.

Follow-ups have been completed at all sites.

NMCSD: Follow up phase: 187. Completed follow up visit – total 72 (36 UC, 36 CL)

WNYVA: Follow up phase: 167, Completed follow up visit – total 109 (63 UC, 46 CL)

VAPA: Follow up phase: 342. Completed follow up visit – total 170 (88 UC, 82 CL)

MAMC: Follow up phase: 269. Completed follow up visit – total 9 (4 UC, 5 CL)

LRMC: Follow up phase: 204. Completed follow up visit – total 15 (8 UC, 7 CL)

TAMC: Follow up phase 150. Completed follow up visit – total 56 (28 UC, 28 CL)

Final outcomes assessments have been completed at all sites. All sites are completing data collection of readmission data for all subjects.

Submission to DSPO for NDI Plus records was completed on 15 February 2017 and acknowledged as received on 16 February 2017. The lead site is completing request to obtain the SSA Death Master File.

Dr. Luxton co-authored a caring contacts implementation paper (in press, Professional Psychology: Research and Practice) with VA colleagues. This paper is not included as an appendix because it was not funded by this project.

## **MONTHS 1-6: Phase I – Preparation and Regulatory Review**

- *Months 1-6:* Obtain IRB approvals to conduct a clinical trial using human subjects  
See status below.
- *Months 2-6:* Hire project staff, including research assistants for all project sites  
Completed.
- *Months 4-6:* Train project personnel, all locations  
Completed.
- *Months 1-6:* Acquire and compile necessary supplies and equipment  
Completed.

## **MONTHS 6-60: Phase II- Implement RCT**

- *Months 6-36:* Recruitment. Identify Soldiers and Veterans who have been hospitalized on psychiatric inpatient units or who otherwise meet inclusion criteria and (a) obtain informed consent; (b) Randomize into Caring Letters (intervention) or Usual Care (control) groups; (c) Collect initial semi-structured interview with research assistant.

Completed.

- *Months 6-60*: Intervention. For each participant randomized to Caring Letter group send emailed letters monthly for 4 months, then every 2 months for 18 months for a total of 24 months.

Completed

- *Months 30-60*: Outcomes Assessments. Conduct post-intervention assessment of study outcomes by email

Completed

### **MONTHS 54-60: Phase III: Analysis and Reporting**

- *Months 54-60*: Prepare and consolidate dataset. (a) Develop and implement data integrity “cleaning” procedures; (b) Obtain, identify and integrate suicide death records (primary outcomes) from National Death Index; (c) Analyze data to evaluate hypotheses.

In progress.

- *Months 57-60*: (a) Prepare and submit final study close out reports to USAMRMC ORP, Human Research Protection Office (HRPO), and Madigan Army Medical Center Department of Clinical Investigation (DCI); (b) prepare manuscripts and presentations for public dissemination of findings.

Not started.

### ***Regulatory Matters***

The team submitted continuing review for Tripler Army Medical Center to MAMC IRB on 09 May 2016 and was approved through 22 June 2017. Continuing review was submitted to MAMC IRB for Landstuhl Regional Medical Center on 03 May 2016 and was approved through 22 June 2017. Continuing review was submitted to MAMC IRB for Madigan Army Medical Center on 29 April 2016 and was approved through 22 June 2017. Continuing review was submitted to MAMC IRB on 03 May 2016 for Naval Medical Center San Diego and was approved through 22 June 2017. Continuing review was submitted to Stanford IRB for Palo Alto and was approved through 31 March 2017. Continuing review was submitted to Buffalo VA Medical Center IRB for VA Western New York and was approved through 23 October 2017.

Continuing review was submitted to HRPO for TAMC on 24 August 2016.

Continuing review was submitted to HRPO for VAPA on 19 August 2016.

Continuing review was submitted to HRPO for MAMC on 11 August 2016.

Continuing review was submitted to HRPO for LRMC on 17 August 2016.

Continuing review was submitted to HRPO for NMCS D on 29 August 2016.

Continuing review was submitted to HRPO for VAWNY on 24 October 2016.

### **Amendments:**

On 25 October 2016, MAMC IRB approved an amendment for the use of Intelius, a web-based application to locate subjects at MAMC.

On 29 November 2016, MAMC IRB, approved an amendment for the use of Intelius at NMCS D, TAMC and LRMC.

### **Submission of Serious Adverse Events:**

Four SAEs were reported at VAPA. One SAE was reported and acknowledged on 02 MAR 2016. The cause of death was multiple blunt force traumas, and was viewed as an accident, not study related. One SAE was reported and acknowledged on 28 April 2016. The cause of death was multiple organ system failure secondary to duodenal ulcer perforation and was not related to study. One SAE was reported on 05 July 2016 for Palo Alto VA. It was noted that the subject was not feeling well and then died the next day at home, this was not related to the study. One SAE was reported on 17 OCT 2016. Upon review of medical records to complete the follow up visit, it was noted that the subject had died, no cause of death was noted in medical record. This was not related to the study.

At VA WNY two SAEs were reported. One SAE was reported and acknowledged on 22 Mar 2016. The cause of death is unknown and not related to the study. One SAE was reported and acknowledged on 12 April 2016. The cause of death is unknown and was not related to the study.

### **Administrative and Logistical Matters**

A No Cost Extension request was submitted on 30 December 2016 for an extension of the period of performance until 31 August 2017. Approval was received on 19 January 2017.

Personnel: The Project Manager at MAMC resigned on 15 July 2016. Previous Project Manager returned to the project and all necessary transition was completed prior to PM leaving the site. The Coordinator at VAHWNY changed from 100% effort to 50% on 09 May 2016.

Equipment: None required at this time.

Materials, supplies and consumables: Materials and required supplies continue to be coordinated in anticipation for data collection and future archive and close-out procedures.

### **Internal Audits**

Dr. Luxton traveled to TAMC the week of 28 Mar 2016 to review the progress for follow-ups and data entry and met with the site PI and CRC on 30 Mar 2016.

Ms. Lisa Thomas conducted a site audit at TAMC the week of 16 May 2016 and there were no significant findings.

### **Key Research Accomplishments:**

- We have enrolled 1,319 participants across six military sites
- Site audits have been conducted at all recruitment sites with no significant findings

### **Reportable Outcomes:**

Dr. Luxton attended the IPR at Ft. Detrick on 13 May 2016 and briefed study progress.

### **Conclusion:**

Final data are still being collected and analysis is not yet complete.

### **References:**

1. Motto JA, Bostrom AG. A randomized controlled trial of post-crisis suicide prevention. *Psychiatry Serv.* 2001; 52(6):828-833.
2. Luxton, D. D., June, J. D. & Comtois, K. A. (2013). Can Post-Discharge Follow-up Contacts Prevent Suicide and Suicide Behavior?: A Review of the Evidence. *Crisis: The Journal of Crisis Intervention and Suicide Prevention.* 34, 32-41.
3. Luxton, D. D., Thomas, E. K., Chipps, J., Relova, R. M., Brown, D., McLay, R., Lee, T., Nakama H., & Smolenski, D. J., (2014). Caring Letters for Suicide Prevention: Implementation of a Multi-Site Randomized Clinical Trial in the U.S. Military and Veteran Affairs Healthcare Systems. *Contemporary Clinical Trials.* 37(2), 252-260. doi: 10.1016/j.cct.2014.01.007

### **Appendices:**

None